REMARKS

Applicants would like to acknowledge, with appreciation, the Examiner's ongoing effort associated with prosecution of this application. The Office Action dated September 17, 2007 has been carefully reviewed. By this Amendment, claims 49 and 125 have been amended, and claim 132 has been cancelled. Applicants request reconsideration of this application in light of the amendments and remarks presented herein.

§112 REJECTIONS

Each of the pending claims was rejected under Section 112 in the 9/17/07 Office Action. Applicants have amended the claims to remove the recitations in question thereby rendering the Section 112 rejections moot.

§103 REJECTIONS – DEVANATHAN/McKELLOP

Claims 49, 50, 52, 55, 125-129, and 132 were rejected under 35 U.S.C. §103 as being unpatentable over U.S. Patent No. 5,645,594 to Devanathan et al. (hereinafter "Devanathan") in view of U.S. Patent No. 6,165,220 to McKellop et al (hereinafter "McKellop"). In this Response, Applicants have amended claims 49 and 125, and cancelled claim 132. Reconsideration of this application is respectfully requested.

In the 1/4/07 Office Action, the Examiner indicated:

> "...it would have been obvious to one of ordinary skill in the art at the time the invention was made to have irradiated the articulating surface of the Devanathan et al. bearing with e-beam irradiation, as taught by McKellop et al., to produce cross-linking on its articulating surface for wear resistance."

In other words, the Examiner proposes to take Devanathan's molded, finished composite bearing and subject it to e-beam irradiation, as taught by McKellop.

The composite prosthetic bearings of Applicants' independent claims 49 and 125 are not formed by surface-gradient crosslinking, but rather are fabricated by molding separate

layers of polyethylene to one another. In the case of independent claim 49, a layer of crosslinked polyethylene is molded to a non-crosslinked layer of polyethylene, whereas in the case of independent claim 125, a first layer of polyethylene that is crosslinked to a first degree is molded to a second layer of polyethylene that is crosslinked to a second, different degree. To more clearly distinguish Applicants' molded composite bearing of claim 49 from surface-gradient crosslinked bearings, Applicants have herein amended claim 49 to recite the notion that non-crosslinked polyethylene is fused to crosslinked polyethylene at the melt-fused interface (i.e., "wherein non-crosslinked polyethylene of the non-crosslinked layer of polyethylene is fused to crosslinked polyethylene of the crosslinked layer of polyethylene at the melt-fused interface"). As such, the interface is formed by the entanglement of the molecules or molecular chains of one dissimilar polyethylene layer with the other.

It was Applicants who first realized that the tensile properties associated with the melt-fused interface between crosslinked and non-crosslinked polyethylene are as strong as at least the weaker of the individual layers (kindly see TABLE I and TABLE II, and the associated discussion, from Applicants' specification for a better understanding of this notion). This is in contrast to earlier beliefs that the flowability limitations of crosslinked polyethylene rendered it unsuitable for molding to other materials. To wit, note the first four lines of column 5 of McKellop where it is noted that the gradual transition associated with gradient crosslinked polyethylene of McKellop's method is preferred "so that there is not a weak interface that could delaminate, i.e., due to a sudden change from crosslinked to non-crosslinked material." Applicants have overcome these existing misbeliefs.

Claim 125 has been amended in a similar manner (i.e., wherein "polyethylene crosslinked to the second degree of the second layer of polyethylene is fused to polyethylene crosslinked to the first degree of the first layer of polyethylene at the melt-fused interface"). Moreover, in the 9/17/07 Office Action it was noted that "crosslinked to a second degree" could be interpreted to mean "zero" (i.e., non-crosslinked). Respectfully, the claim positively recites

that the second layer is indeed crosslinked. However, to more clearly connote this, claim 125 has been amended to recite the "second layer of polyethylene is radiation crosslinked to a second degree". As such, it is clear that each of the two layers is indeed crosslinked to some degree.

The combination of Devanathan and McKellop does not arrive at the invention of amended independent claims 49 and 125. Namely, the combination does not teach fusing non-crosslinked polyethylene to crosslinked polyethylene at the melt-fuse interface, nor does it teach fusing polyethylene crosslinked to a one degree to polyethylene fused to another degree at the melt-fuse interface. By contrast, subjecting Devanathan's finished bearing to McKellop's surface crosslinking would not create a bearing with dissimilar materials fused at the melt-fuse interface, but rather would create a crosslinked gradient in the first zone (i.e., layer 12) of Devanathan's bearing. This is true for the very reasons put forth by the Examiner in the 1/4/07 Office Action and relied upon in the 9/17/07 Office Action. In particular, the Examiner believes that Devanathan's intent of a bearing having increased stiffness and creep resistance is not destroyed by surface-gradient crosslinking that does not extend into the bulk of the implant. This also appears consistent with the teachings of McKellop where it is warned not to penetrate too deeply with e-beam irradiation in order to maintain the mechanical properties of non-crosslinked polyethylene throughout the bulk of the implant (see, e.g., McKellop column 6, lines 30-46). With this in mind, no one skilled in the art utilizing surface-gradient crosslinking to crosslink Devanthan's bearing, as proposed by the Examiner, would crosslink Devanathan's bearing layer (i.e., layer 12) all the way down to the melt-fused interface since to do so would, *ipso facto*, require a significant portion of the underlying layer(s) of the implant beyond the melt-fused interface to likewise be crosslinked. This is true since the dosage required to produce crosslinking at the melt-fused interface would cause crosslinking, perhaps substantial crosslinking, to occur in the implant at a depth beyond the melt-fused interface.

In other words, if one were to attempt to crosslink the bearing layer 12 of Devanthan's implant down to the melt-fused interface, it would, *ipso facto*, cause crosslinking

into the portion of the implant containing PMMA (i.e., Devanathan's layer 19). Realizing that PMMA was added to Devanathan's implant to increase the stiffness and creep resistance of Devanathan's implant (see Devanathan at column 2, lines 37-45) and also realizing that, as pointed out in Applicants previous Response to Office Action dated 10/17/06, it is known that crosslinking can lead to a reduction in stiffness and creep resistance, Applicants argue that no one skilled in the art would crosslink the PMMA-containing layer of Devanathan's implant. To do so would be self-defeating. Namely, Applicants argue that no one skilled in the art would add material the underlying layer of the implant to increase its stiffness and creep resistance (i.e., PMMA) only to then subsequently subject the same underlying layer of the implant to a process which reduces stiffness and creep resistance (i.e., crosslinking). Based on the above-noted comments from the 1/4/07 Office Action, it appears that the Examiner likewise believes this to be true.

As such, the only combination of Devanathan and McKellop (to the extent they are even properly combinable) that doesn't destroy the intended purpose of Devanathan (i.e., to produce a bearing with increased stiffness and creep resistance) necessitates that the entirety of the gradient crosslinking be confined to the polyethylene bearing layer 12. To do so produces a bearing that fails to read on Applicants amended claims since non-crosslinked polyethylene would not be melt-fused to crosslinked polyethylene at the melt-fused interface (as in claim 49), nor would polyethylene crosslinked to one degree be melt-fused to polyethylene crosslinked to another degree at the melt-fused interface (as in claim 125).

Moreover, even if one were to disregard the teachings of Devanathan and utilize the McKellop method to crosslink Devanathan's bearing down to the molded interface (which one wouldn't do since it would destroy Devanathan's intended purpose, but this is merely for argument's sake), the combination would not arrive at the invention of claims 49, 125. In particular, if one were to attempt to crosslink the bearing layer 12 of Devanthan's implant down to the melt-fused interface, it would, *ipso facto*, cause crosslinking into the implant on the other

side of the interface (i.e., into Devanathan's layer 14). At this point, similar materials would be fused to one another at the melt-fused interface (e.g., crosslinked polyethylene to crosslinked polyethylene) as opposed to the claimed interface of dissimilar materials (e.g., non-crosslinked polyethylene to polyethylene).

In summary, the Devanathan/McKellop combination does not arrive at the invention of currently amended claims 49 and 125. Nor can the the Devanathan/McKellop combination be further modified to arrive at the invention of currently amended claims 49 and 125 without destroying the intent of Devanathan's invention. As such, it is respectfully requested that the §103 rejection of claims 49 and 125 be withdrawn. Because the remaining claims are dependent on either claims 49 or 125, it is respectfully requested that the rejection of these claims likewise be withdrawn.

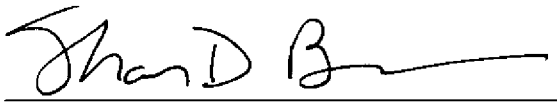
CONCLUSION

In view of the foregoing, it is submitted that this application is in a condition for allowance. Action to that end is hereby solicited.

It is respectfully requested that, if necessary to effect a timely response, this paper be considered as a Petition for an Extension of Time sufficient to effect a timely response and shortages in other fees be charged, or any overpayment in fees be credited, to the Account of Barnes & Thornburg, Deposit Account No. 10-0435 with reference to file 265280-68002.

Respectfully submitted,

BARNES & THORNBURG LLP



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